OCT 0 8 2008

510(k) Summary:

Applicant Information:

Name: The Medical Company
Address: P.O. Box 2116
3800 CC Amersfoort
The Netherlands

Phone: +31 33 465 0113
Fax: +31 33 465 2191
Email: info@themedicalcompany.nl

Contact: Mr. Harm Jaap Smit

Establishment registration number: not available yet

Manufacturer:

Name: MediTop BV
Address: Vlasakker 22
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The Netherlands

Phone: +31 348 566 100
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Email: info@meditop.nl

Contact: Mr. Gé van Breukelen

Trade Name:

Wound Drainage Pump Exsudex™

Device Classification:

Powered Suction Pump
Regulation per FDA 21 CR 878.4780
Class II
Product code: BTA
Review Panel: General & Plastic Surgery

i. **Device name**: Exsudex™ Negative Pressure Wound Drainage pump

ii. **Classification name**: Powered suction pump (per 21 CFR 878.4780)

iii. **Substantial equivalence**: V.A.C.™ Plus 510(k) No.K992448
Ambulatory V.A.C. 510(k) No.K971548
Medela Vario 5 10(k) No. K983552
Versatile 1 510(k) No. K052456

iv. **Device description**:

The Exsudex™ unit is a compact portable suction device that can be powered by either an internal battery pack or wall current and is compatible with U.S. electrical standards. The pump will be used in combination with accessory kits to create localized topical negative pressure and promote wound healing by drainage of fluids and infected materials from the wound and wound bed into a disposable canister.

The Exsudex™ consists of a medium sized housing that contains a vacuum pump and control system with a location for a fluid canister system. There is also a bacterial filter which is plugged directly into a housing in the pump and replaced as necessary. Accessories include a bed clamp, infusion pole clamp and carry bag. For the expanded indication of use for wound healing the unit is used in conjunction with accessory kits conforming to the guidelines for dressings developed by Chariker et al[1] already available in the U.S. market. This kit consists of individually reviewed medical components that have added instructions for use. The kits are considered "Convenience Kits", falling under the General Surgical classification (see 21 CFR 878.4800.)
To use the pump, the suction tube must be connected to the canister and to the drain.
After checking the set up and confirming connection between the canister and the drain, the Exsudex™ is activated by pressing the start/stop button.

To ensure the maintenance of the desired level pressure, Exsudex™ monitors and controls:

- The buildup of pressure
- pressure loss
- pressure tolerance

The Exsudex™ is intended for acute, institutional, and long-term care use and only when prescribed by a physician. Product may be indicated for patient home-care, when carefully monitored by licensed home health-care providers, and only when prescribed by a physician.

CAUTION
Federal law restricts this device to sale by or on the order of a physician.

Canisters
The machine may be used with a disposable canister which is intended for medical use and is registered appropriately. The canister is disposable and can be supplied in a range of sizes up to a maximum fluid capacity of 1300cc and contains an overflow shut off valve. It is secured to the Exsudex™ unit by means of a slide-fit housing on the back of the pump.

The canister intended for primary use with the device is a 1200cc disposable canister, with a secure press-on lid, designed to tightly affix during transport and disposal, eliminating the risk of cross-contamination. The canister lid has a built-in pour spout. The canister is equipped with a filter with positive shut-off value that effectively traps aerosolized microorganisms and particulate matter and that prevents fluid overflow. The canister is easy to read with etched and printed graduations which ensure total volume accuracy and easy-to-read measurements. The canister has a smudge-free surface which provides adequate space for marking patient information. The canister is non-sterile and is designed to be discarded when full, partially full, or on completion of patient care.

Single use disposables
For the indication of use for wound healing, the device is used in conjunction with accessory kits conforming to the guidelines developed by Katherine Jeter and Dr. Mark Chariker.[1] Similar kits are already available in the U.S. market. The kits consist of individually reviewed medical components from existing manufacturers that have met the regulatory requirements of the FDA (see 21 CFR 878.4800) and include separate, additional instructions for use.

The Kits include:

1. Silicone or Wound drain
2. Connecting tubing
3. Impregnated gauze
4. Gauze fill material
5. Polyurethane Cover dressing
6. Skin prep

All products, including canister and disposable kit of individual components are not designed for cleaning or reuse and should be properly discarded after patient use. The sale or use of this device must be by or on the order of a physician.

Indications for use
The Exsudex™ Wound Drainage Device is indicated for patients who would benefit from the application of negative pressure to the area of a wound to promote wound healing by drainage of fluids and infected materials from the wound and wound bed.

[1] Effective Management of Incisional and Cutaneous Fistulae With Closed Suction Wound Drainage, Mark E. Chariker MD, Katherine F. Jeter, Ed.D., et al, Contemporary Surgery, Vol. 34 June 1989, pp. 59-63.

Contraindications:
The Exsudex™ is contraindicated for the following reasons for Wound Treatment:

- Presence of necrotic tissue
- Malignancy (except for quality of life reason for terminal patients)
- Untreated Osteomyelitis
- Untreated malnutrition
- Use on exposed arteries, veins or organs.

Precautions:

- Patients on anticoagulants or with difficult hemostasis should be treated with caution and have to be controlled regularly for bleeding.
- Patients with infections in the wound and or other parts of the body have to receive proper systemic treatment.
- Non-compliant patients
- The Exsudex™ has not been studied on pediatric patients.

General Precautions for all indications for use:

- Health care provider must evaluate patient to ensure that use of the Exsudex™ is an appropriate therapy.

Warnings

- Physicians should consider patient's size and weight when prescribing device.
- The device is MR unsafe and must be disconnected from the patient prior to MRI.
- The device may be used in the event that defibrillation is needed, provided there is no electrical contact between patient and device. In such case the device must be disconnected. Be sure to remove the dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit transmission of electrical energy and/or patient resuscitation.
- The device may not be used in a hyperbaric oxygen chamber.
- To prevent unintentional gauze retention, all dressings are removed from the wound and wound bed. Upon removal of dressing(s), the wound bed should be cleaned in accordance with standard wound care practices, prior to the application of new sterile dressing.
- If necessary all wounds should be debrided prior to application of the therapy and/or dressings.
- Ensure there are no pockets left in the wound bed after application of the dressing.
- Infected wounds may need more frequent dressing changes, up to twice a day, and the patient and the wound must be inspected regularly for signs of increased infection or sepsis.
- Patients who do not have adequate haemostasis, and on whom anticoagulation or platelet aggregation inhibitors are being used have an increased risk of bleeding with or without the Exsudex™.
- The device has not been studied in pediatric patients.
- All arteries, veins, tendons, ligaments nerves and other organs have to be covered completely prior to application of the Exsudex™.
- Infected tissue such as blood vessels may have a weakened structure and have to be treated with care. Infected blood vessels may bleed more readily than normal blood vessels
- The device is intended for acute, institutional, and long-term care use and only when prescribed by a physician. Product may be indicated for patient home-care, when carefully monitored by licensed home health-care providers, and only when prescribed by a physician.

v. Summary of the technological characteristics of the device compared to the predicate device.
Each of the devices providing NPWT consists of the same basic technology, and do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness. Each device consists of a vacuum control unit with an integrated collection canister and power supply (battery or AC). The primary differences in these models relate to size and weight.

All models of the NPWT family of devices are designed to help promote wound healing, through the application of controlled negative pressure to the surface and margins of the wound. This negative pressure therapy is applied through the dressing positioned in the wound cavity or over a flap or graft. This pressure distributing dressing helps remove fluids from the wound. The devices are designed to treat wounds such as chronic, acute, traumatic, sub-acute and dehisced wounds; partial-thickness burns; ulcers (such as diabetic or pressure); flaps; and grafts.

vi. Testing

Verification and validation testing of the Exsudex™ device, including functional performance testing and electrical leakage testing, was conducted in accordance with established design control procedures.

vii. Conclusions

Based upon testing as well as extensive clinical use in Europe, the Exsudex™ Wound Drainage Device has the same intended uses as the predicate devices, with similar technological characteristics. The system performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

The Medical Company
% Kema Quality B.V.
Mr. J. A. Van Vugt
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K082311
Trade/Device Name: Exsudex™ Wound Drainage Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: September 25, 2008
Received: September 30, 2008

Dear Mr. Van Vugt:

This letter corrects our substantially equivalent letter of October 8, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

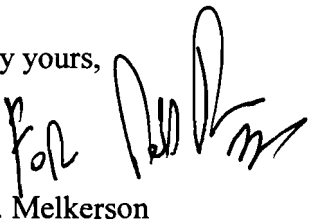
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K082311

Device Name: Exsudex™ Wound Drainage Pump

Statement:
The Exsudex™ Wound Drainage Device is a compact, portable device indicated for patients who would benefit from the application of negative pressure to the area of a wound, for the aspiration and removal of surgical fluids, irrigation fluids, tissue (including bone), gases, bodily fluids or infectious materials either during surgery or at the patient's bedside particularly as the device may promote wound healing .

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082311